

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This document relates to:  
*All Actions*

No. 19-md-2875-RBK

Honorable Robert Kugler  
Special Master Thomas Vanaskie

**CERTIFICATION OF STEPHEN LAGANA, M.D.**

1. This Certification is submitted as my direct testimony for the *Daubert* hearing, and is based on my personal knowledge.

2. I was questioned during my deposition about whether I began my analysis from the “null hypothesis,” which is a concept applied in statistics, requiring the starting point for a statistical analysis of data to be the assumption that there is no statistical relationship between an effect and proposed cause. I did not perform a statistical analysis as would be performed by a biostatistician. I applied the weight of evidence and Bradford-Hill methodologies.

3. The Defendants’ initial brief mischaracterizes what I did, stating, “Dr. Lagana explicitly began his research with an assumption that general causation was proven and then embarked on a literature search intent on finding evidence to support that assumption.” (Defense brief, page 9). That is not what I did in forming my general causation opinions.

4. In forming my opinions regarding the general causation question of whether taking the NDMA and NDEA contaminated valsartan pills increased the risk of cancer for people taking the pills, or stated another way whether this could cause or contribute to causing cancer in the people taking the pills, I did not start from the premise that the answer was yes.

5. I evaluated and took into account the various categories of medical and scientific literature and evidence discussed in my report and my deposition, and reached my opinions based on that analysis. I did not start from an assumption that general causation was established.

6. On pages 11-12 of my report I discussed the concept of differential diagnosis in the treatment of a specific patient, as background, when I stated: “the crucial point is that we start from the assumption that exposure to a human carcinogen contributed to carcinogenesis in a patient with a cancer unless there is convincing evidence to the contrary.” That was a discussion of the formation of a differential diagnosis in a specific patient. This would apply, for example, if a patient with cancer was a lifetime cigarette smoker; in that instance, one would have a high index of suspicion and place cigarette smoking high on the differential diagnosis as at least a contributing cause of the cancer, in the absence of convincing evidence to the contrary in that patient’s case. That was not a reference to the methodology I applied in forming my general causation opinions, as my opinions to date are not focused on whether any particular patient developed cancer in whole or in part due to consuming contaminated valsartan pills. I mentioned this for context because it is my understanding that one would need to first opine that general causation exists, before determining whether and how to include the consumption of the contaminated valsartan pills in the differential diagnosis for a specific patient when the litigation reaches the specific causation phase.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: February 23, 2022.

A handwritten signature in black ink, appearing to read 'Stephen Lagana', written over a horizontal line.

Stephen Lagana, M.D.